

# **EXHIBIT E**

**Fourth Supplemental Declaration of Andrew E. Lorincz, M.D.**



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: James P. Elia )  
Serial No.: 09/064,000 ) Group Art Unit: 1646  
Filed: April 21, 1998 ) Examiner: Elizabeth C. Kemmerer, Ph.D.  
For: METHOD FOR GROWTH )  
OF SOFT TISSUE )

**FOURTH SUPPLEMENTAL DECLARATION  
OF ANDREW E. LORINCZ, M.D.**

I Andrew E. Lorincz declare as follows:

1. I reside at 16135 NW 243<sup>rd</sup> Way, High Springs, Florida 32643-3813.
2. My Curriculum Vitae is attached as Exhibit A to my Declaration of February 12, 2001. Paragraph 4 of my Declaration and my Supplemental Declaration of November 8, 2004 provide additional information regarding my background and experience.
3. I have read and understood the disclosures of the above-referenced patent application at page 20, line 10 through page 21, line 15; at page 37, lines 19-25; at page 44, line 19 through page 46, line 16; and at page 47, line 22 through page 48, line 15. Such disclosures are the same as I read and understood in my

previous Declaration. A copy of such disclosures was attached to my Third Supplemental Declaration as Exhibit A.

I have also read and understood additional disclosures of the above-referenced patent application at page 33, lines 8-10; page 40, line 20 through page 43 line 3; page 44, lines 12 and 13; page 48, lines 13-15; page 53, line 1 through page 56, line 25; and page 62, lines 1-10. A copy of such additional disclosures was attached to my Third Supplemental Declaration as Exhibit B.

4. I note that the disclosures referenced in above Paragraph 3 relate to using a growth factor for promoting the growth of soft tissue, and more specifically, to a method of using a cell, such as a stem cell, to grow soft tissue, such as an artery.
5. I have read and understood the claims set forth in the attached Fourth Supplemental Declaration Exhibit A and have been informed that such claims will be concurrently presented in the above-referenced patent application with this Fourth Supplemental Declaration.
6. Based upon above Paragraphs 3-5, it is my opinion that introducing a growth factor, including cells, and more specifically, stem cells, in the body of a human patient will predictably result in the growth of soft tissue, such as an artery, which will integrate itself into pre-existing tissue of the body thereby forming a unified whole.

7. Based upon above Paragraphs 3-5, it is my opinion that one skilled in the medical arts, armed with the knowledge in such paragraphs, would be able to practice the method set forth in Exhibit A without need for resorting to undue experimentation.
8. Declarant states that the above opinion was reached independently.

Declarant understands that (1) any willful false statements and the like made herein are punishable by fine or imprisonment, or both (18 U.S.C. 1001) and may jeopardize the validity of the application or any patent issuing thereon, and (2) that all statements made of Declarant's own knowledge are true and that all statements made on information and belief are believed to be true.

Further Declarant sayeth not.

Date: 11-13-07

Andrew E. Lorincz  
Andrew E. Lorincz, M.D.

# **FOURTH SUPPLEMENTAL DECLARATION**

## **EXHIBIT A**

## **CLAIMS**

**EXHIBIT A**

**CLAIMS**

**APPLICATION SERIAL NO. 09/064,000**

Claim 403                    A method for growing and integrating tissue consisting of desired soft tissue at a selected site in a body of a human patient wherein said desired soft tissue comprises a desired artery comprising the steps of:

- (a) locally injecting stem cells into said body at said selected site;
- (b) forming a bud at said selected site; and
- (c) growing said desired artery from said bud wherein said artery integrates itself into said body of said human patient at said selected site.

Claim 404                    The method of claim 403, wherein said selected site comprises a damaged site in a leg of said patient and said stem cells are injected intramuscularly.

Claim 405                    The method of claim 403, wherein said selected site comprises a damaged site in a heart of said patient and said stem cells are injected intramuscularly.

Claim 407                    The method of claim 403, wherein said stem cell comprises a living stem cell harvested from bone marrow.

Claim 408      The method of claim 407, wherein said bone marrow is from said patient.

Claim 409      The method of claim 403, wherein said stem cell comprises a living stem cell harvested from blood.

Claim 410      The method of claim 409, wherein said blood is from said patient.

Claim 411      The method of claim 403 further comprising determining blood flow through said desired artery.

Claim 412      The method of claim 403 further comprising observing said desired artery.